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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/098,690	03/15/2002	Stephen Grimes	1102865-0302	6943

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EXAMINER	
KIM, SUN U	
ART UNIT	**PAPER NUMBER**
1723	

DATE MAILED: 01/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/098,690	GRIMES ET AL.	
	Examiner	Art Unit	
	John Kim	1723	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 March 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-6* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 March 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/10/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1, 3 and 5-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Jonsson (US Pat. No. 4,579,662). Jonsson teaches a system comprising an filter device (10) having a membrane with a pore size of 0.2 micron i.e. ultrafiltration/concentration means, a reaction vessel (15) connected to the filter device (10), a backwash reservoir (25) connected to the filter device (10) and a pump on a tube (13) interconnected between the filter device (10) and the reaction vessel (15) (see figures 1-4; col. 1, line 66 – col. 2, line 6; col. 3, lines 28-36; col. 4, line 6 – col. 5, line 66)(claim 1). Regarding claim 3, Jonsson teaches a three way valve (75) selectively connected to the reaction vessel (15) and the filter device (10) and situated between the reaction vessel (15) and the filter device (10) and the backwash reservoir (25) (see figure 6; col. 8, lines 15-55). Regarding claim 5, Jonsson teaches that the filter device (10) is connected to the permeate reservoir (19) (see figures 2-4; col. 4, lines 20-24). Regarding claim 6, the reaction vessel (15) is connected to the concentrated suspension vessel (21) (see figure 6; col. 6, lines 19-23). Recitation of "A closed system for the continuous liquid phase modification and/or conjugation of proteins, purification and concentration thereof" is an intended use of the apparatus. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art

apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

3. Claims 1 and 4-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Breslau et al (US Pat. No. 4,986,918). Breslau et al teach a system comprising an ultrafiltration membrane module, a reaction vessel (T1) connected to the ultrafiltration membrane separation module, a backwash reservoir (T2) connected to the ultrafiltration membrane separation module and a pump (P) interconnected between the ultrafiltration membrane separation module and the reaction vessel (T1) (see figures 1-7; col. 4, line 10 – col. 6, line 68)(claim 1). Regarding claim 4, Breslau et al teach that the membranes used in ultrafiltration may be in spiral wound configuration (see col. 1, lines 43-45). Regarding claim 5, Breslau et al teach that the ultrafiltration membrane separation module is connected to the permeate reservoir (T2) (see figures 3-7). Regarding claim 6, the reaction vessel (T1) receives purified concentrated product from the ultrafiltration separation module (see figures 1-4). Recitation of "A closed system for the continuous liquid phase modification and/or conjugation of proteins, purification and concentration thereof" is an intended use of the apparatus. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

4. Claims 1 and 4-6 are rejected under 35 U.S.C. 102(e) as being anticipated by Buckley et al (US Pat. No. 5,342,863). Buckley et al teach a system comprising an ultrafiltration membrane module (1), a reaction vessel (4) connected to the ultrafiltration membrane module (1), a backwash tank connected to the ultrafiltration membrane module (1) and a pump (3)

interconnected between the ultrafiltration membrane module (1) and the reaction vessel (4) (see figures 1-2; col. 4, lines 36-60; col. 6, line 28 – col. 8, line 34; col. 10, line 25 – col. 11, line 9; col. 14, lines 17-26)(claim 1). Regarding claim 4, Buckley et al teach that the ultrafiltration membranes is a spiral wound membrane cartridge (see col. 7, lines 48-57). Regarding claim 5, Buckley et al teach that the permeate is collected in a cleaning tank (see col. 14, lines 18-21). Regarding claim 6, the reaction vessel (4) receives purified concentrated product from the ultrafiltration membrane module (1) via line 11 (see figure 1). Recitation of "A closed system for the continuous liquid phase modification and/or conjugation of proteins, purification and concentration thereof" is an intended use of the apparatus. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1, 3 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meier (US Pat. No. 5,262,053) in view of Moller (US Pat. No. 5,620,065). Meier teaches a system comprising an filter device (2) with ultrafiltration membrane, a reaction vessel (7) connected to the filter device (2), a backwash source (18) connected to the filter device (10) and a pump (9) interconnected between the filter device (2) and the reaction vessel (7) (see figure 1; col. 5, line 61 – col. 7, line 18). Claim 1 essentially differs from the apparatus of Meier in reciting a

backwash reservoir. Meier teaches that backwash source is water or cleaning liquids which is directed to the permeate side of the membrane (see col. 6, lines 11-15; col. 7, lines 10-17). Moller teaches a system comprising ultrafiltration membrane device(13) with a backwash tank (18) for backwashing fluid to the permeate side of membrane to remove contaminants from the membrane (see figure 1; col. 5, lines 64-65; col. 11, lines 21-58; col. 13, lines 13-48). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the apparatus of Meier to include a backwash reservoir containing water or cleaning liquids connected to the ultrafiltration membrane device (2) for effectively storing the backwash fluid to backflush the membrane as suggested by Moller. Regarding claim 3, Meier teaches a three way valve (17) selectively interconnected and situated between the reaction vessel (7) and the filter device (2) and the backwash source (18) (see figure 1; col. 6, lines 11-15; col. 6, line 56 - 17). Regarding claim 5, Meier teaches that the filter device (2) is connected to the permeate reservoir (19) (see figure 1; col. 5, line 68 – col. 6, line 2).

7. Claims 1, 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brochure from AMICON re "Operating Principles of Ultrafiltration Systems" (hereinafter referred to as Pub 750) in view of Breslau et al. Pub 750 teaches a ultrafiltration system comprising an ultrafiltration membrane device, a reaction vessel connected to the ultrafiltration membrane device, and a pump interconnected between the ultrafiltration membrane device and the reaction vessel (see figures 1-2; pages 1-2). Claim 1 essentially differs from the apparatus of Pub 750 in reciting a backwash reservoir being fluidly connected to the ultrafiltration means. Pub 750 recognizes that the ultrafiltration cartridges retain LPS pyrogens and pyrogens are removed by periodic flushing (see pages 3-4). Moller teaches a system comprising

ultrafiltration membrane device (13) with a backwash tank (18) for backwashing fluid to the permeate side of membrane to remove contaminants from the membrane (see figure 1; col. 5, lines 64-65; col. 11, lines 21-58; col. 13, lines 13-48). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the apparatus of Pub 750 to include a backwash reservoir containing backwashing fluid connected to the ultrafiltration membrane device for effectively storing the backwash fluid to backflush the membrane as suggested by Moller. Regarding claim 5, Pub 750 teaches that the ultrafiltration membrane device is connected to the permeate reservoir (see figures 1-2). Regarding claim 6, Pub 750 teaches that reaction vessel containing process fluid receives concentrated product (see figures 1-2).

8. Claims 1, 4 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over AMICON Brochure re Spiral-Wound/Hollow Fiber System (hereinafter referred to as AMICON) in view of Moller. AMICON teaches a ultrafiltration system comprising an ultrafiltration membrane device, a reaction vessel connected to the ultrafiltration membrane device, and a pump interconnected between the ultrafiltration membrane device and the reaction vessel (see figure 8 on page 25; page 24). Claim 1 essentially differs from the apparatus of AMICON in reciting a backwash reservoir being fluidly connected to the ultrafiltration means. AMICON recognizes that the performance of ultrafiltration cartridges is affected by accumulation of retained macrosolutes at the membrane surface and suggests that producing adequate fluid velocity of recirculation rates or prefiltering the solution with a 100 micron screen to prevent plugging of the cartridge flow channels (see page 17). Moller teaches a system comprising ultrafiltration membrane device (13) with a backwash tank (18) for backwashing fluid to the

permeate side of membrane to remove contaminants from the membrane (see figure 1; col. 5, lines 64-65; col. 11, lines 21-58; col. 13, lines 13-48). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the apparatus of Pub 750 to include a backwash reservoir containing backwashing fluid connected to the ultrafiltration membrane device for effectively storing the backwash fluid to backflush the membrane as suggested by Moller to prevent plugging of the cartridge flow channels. Regarding claim 4, AMICON teaches a spiral wound/hollow fiber diafiltration cartridge (see page 54, 16). Regarding claim 6, AMICON teaches that feed tank i.e. reaction vessel containing feed fluid receives concentrated product (see figure 6 on page 16).

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. References cited in PTO-892 teaches various systems with backwashing or backflushing capability.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Kim whose telephone number is (571) 272-1142. The examiner can normally be reached on weekdays from 8:30 A.M. to 5:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker, can be reached on (571) 272-1151. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

John Kim
Primary Examiner
Art Unit 1723

J. Kim
January 5, 2006